

Serial No. 09/942,938  
Amendment Dated November 5, 2003  
Reply to Office Action dated May 6, 2003

Docket No. CI-0004

### **REMARKS/ARGUMENTS**

Claims 1-53, 55-57 and 59-86 are pending in this application. Claims 1-4 and 59-85 are withdrawn, claims 54 and 58 are cancelled without prejudice or disclaimer, claims 5-7, 10, 24-31, 34-37, 39-40, 42, 46, 61-67 and 70-77 are amended and claim 86 is added. The amendments introduce no new matter. Reconsideration in view of the above amendments and following remarks is respectfully requested.

#### **I. 35 U.S.C. §112, second paragraph**

The Office Action rejects claims 5-58 under 35 U.S.C. §112, second paragraph. Applicants respectfully submit the above amendments obviate this ground of rejection with respect to the remaining claims. Specifically, the claims have been amended to recite that the claimed method includes “reducing the temperature below ambient temperature.” Withdrawal of the rejection is respectfully requested.

#### **II. Double Patenting**

The Office Action rejects claims 5-58 on the grounds of obviousness-type double patenting. As application 09/960,704 has not been patented, Applicants respectfully submit that this is a provisional rejection and that Applicants may file a Terminal Disclaimer upon allowance of either this application or application 09/960,704. Applicants respectfully request the

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provisional obviousness-type double patenting rejection be stayed until the claims in question have been patented.

### III. 35 U.S.C. §102(e)

The Office Action rejects claims 5, 8-15, 33-39, 42, 45-46, 48-49 and 53-54 under 35 U.S.C. §102(e) over Kent (U.S. Patent No. 6,171,549). Since Kent fails to disclose all of the features of the claims, the rejection is respectfully traversed.

Applicants respectfully submit that all pending claims ultimately depend from claim 5, which includes at least the features of applying to a preparation of one or more digestive enzymes that is sensitive to radiation a stabilizing process of reducing the temperature to a temperature below ambient temperature. Kent clearly does not disclose a method comprising reducing the temperature below ambient temperature of a preparation containing one or more digestive enzymes, as presently claimed.

The Kent reference does not disclose any reduction of temperature in any capacity. Rather, only a single temperature of 23°C (ambient temperature) is disclosed in Kent. See Kent column 4, line 66, for example. Therefore, the present claims are not anticipated by Kent.

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For at least the reasons set forth above, Applicants respectfully submit that claim 5 is allowable. Claims 8-15, 33-39, 42, 45-46, 48-49 and 53 depend from claim 5, and are allowable for at least the same reasons as claim 5. Claim 54 has been cancelled without prejudice or disclaimer, therefore the rejection is moot. Withdrawal of the rejection is respectfully requested.

**IV. 35 U.S.C. §103(a)**

The Office Action rejects claims 5-58 under 35 U.S.C. §103(a) over Kent. Claims 54 and 58 have been cancelled without prejudice or disclaimer, therefore the rejection of these claims is moot. Since Kent fails to disclose or suggest all of the features of the remaining claims, the rejection is respectfully traversed.

Applicants submit that claim 5 includes at least the feature of applying to a preparation of one or more digestive enzymes that is sensitive to radiation a stabilizing process of reducing the temperature below ambient temperature, which is not recognized as a result effective variable by Kent. As mentioned above, Kent does not disclose or suggest a method comprising reducing the temperature, nor does it suggest temperature as being result effective. Thus, the Kent reference does not disclose or suggest any reduction of temperature in any capacity. As mentioned above, only a single temperature of 23°C (ambient temperature) is disclosed in Kent. Therefore, the present claims are not rendered obvious by Kent.

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Applicants respectfully submit that for the reasons discussed above with respect to Kent, Kent does not disclose or suggest all of the features of at least claim 5. Therefore, claim 5 is allowable. Claims 6-53 and 55-57 depend from claim 5, and are allowable for at least the same reasons as claim 5. Withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, Laura L. Lee, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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